HFA-305

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

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January 27, 2000

Lynn K. Pershing, Ph.D.
University of Utah
Department of Dermatology
University of Utah Hospital
50 North Medical Drive
Salt Lake City, Utah 84132

Dear Dr. Pershing:

I am writing in response to your letter of October 30, 1999 to Dr. Janet Woodcock, Director, Center for Drug Evaluation and Research (CDER) expressing your support of the Food and Drug Administration's (FDA) proposal to allow manufacturers to substitute skin tape stripping for pharmacodynamic measurements or comparative clinical trials. I apologize for the delay in responding to your letter.

Thank you for taking the time to write to the FDA to express your interest and comments on this subject. You can be sure that the Agency will continue to base any decision on sound science.

As you know, on June 18, 1998, the FDA published a Federal Register Notice announcing the availability of a guidance for industry entitled, "Draft Guidance for Industry on Topical Dermatological Drug Product NDA's and ANDA's -- In Vivo Bioavailability, Bioequivalence, In Vitro Release and Associated Studies." This draft guidance is intended to provide recommendations to sponsors of new drug applications (NDA's), abbreviated new drug applications (ANDA's), and supplements who intend to perform bioavailability and bioequivalence studies for topically applied dermatological drug products during either the preapproval or postapproval period. The FDA welcomes comments, and I have forwarded a copy of your letter to the Dockets Management Branch for inclusion in the docket (Docket No. 98D-0388). I have also forwarded a copy of your letter to the Glaxo Citizens Petition Docket (Docket No. 99P-0389/CP-1).

Thank you for writing. Please do not hesitate to contact us again if you have further questions or comments.

Sincerely,

Theresa M. Martin
Executive Secretariat Staff (HFD-6)
Center for Drug Evaluation and Research

99P-0389

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